

REMARKS

Status of the Claims and Request for Rejoinder of Claims 4 and 5

After entry of the instant Amendment, claims 1-10 are now pending in the present application. Claim 1 is independent. Claims 2-5 stand withdrawn as being drawn to nonelected subject matter.

Claim 1 has been amended and new claims 6-10 have been added. Amendments to claim 1 and the new claims are supported throughout the specification as filed. Thus, no new matter has been added by way of amendment to the claims.

In view of the amendments made to claim 1 and the patentability arguments made below, Applicants respectfully request that the Examiner consider rejoining withdrawn claims 4 and 5.

Reconsideration of this application, as amended, is respectfully requested.

Priority under 35 U.S.C. § 119

Applicants thank the Examiner for acknowledging Applicants' claim for foreign priority under 35 U.S.C. § 119, and receipt of certified copies of the priority documents.

Objection to the Abstract

The Examiner has objected to the Abstract of the Disclosure for containing grammatical errors. In order to overcome this objection, Applicants have amended the Abstract of the Disclosure to correct the grammatical errors. A Substitute Abstract is attached hereto.

Accordingly, reconsideration and withdrawal of this objection are respectfully requested.

Specification Objection

The Examiner has objected to the specification stating that the sequence appearing on page 11 of the Specification is not identified by a SEQ ID NO. The sequence pointed out by the Examiner is identified as SEQ ID NO:21 elsewhere in the Specification. Applicants have amended the specification at page 11 to indicate SEQ ID NO:21.

With regard to the Notice to Comply, the Sequence Listing submitted April 30, 2010, was accepted and included SEQ ID NO:21. Thus, in view of the amendment to page 11 of the specification, Applicants respectfully submit that a new Sequence Listing is not required.

Reconsideration and withdrawal of this objection are respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph

Claim 1 stands rejected under 35 U.S.C. § 112, first paragraph, as failing to meet the enablement requirement. This rejection is respectfully traversed.

In the Office Action, it is alleged that the specification is only enabling for an HLA-E chimeric molecule that has the entire $\alpha 2$ domain, the latter part of the $\alpha 2$ domain or the first portion of the latter part of the $\alpha 2$ domain replaced with the corresponding HLA-G1 domain portion, and optionally having the SP of HLA-G1.

Claim 1 has been amended to recite that when the claimed HLA-E chimeric molecule is expressed in a nonhuman mammal cell, it is expressed at the cell surface. Further, new claims 6-8 have been added and are directed to embodiments that the Examiner indicated were enabled by the Specification.

Applicants respectfully submit that the claims, as amended, comply with the enablement and written description requirements of 35 U.S.C. § 112, first paragraph. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, as being unclear. This rejection is respectfully traversed.

In order to obviate this rejection, Applicants have amended claim 1 to correct each of the deficiencies specifically pointed out by the Examiner. Applicants respectfully submit that claim 1, as amended, particularly points out and distinctly claims the subject matter which Applicants regard as the invention. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejections under 35 U.S.C. §§ 102(a) and 102(b)

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Strong et al., J Biol Chem, February 14, 2003, Vol. 278, No. 7, pages 5082-5090 (hereinafter "Strong") as evidenced by an admission in the Specification at SEQ ID NO:13 and as evidenced by Matsunami et al., "Identification of amino acid positions involved in HLA-E expression," J

Biochem, 2008, Vol. 143, pages 641-647 (hereinafter "Matsunami"). This rejection is respectfully traversed.

Strong does not teach HLA-E chimeric molecules with a signal peptide (SP) having the sequence of SEQ ID NO:21. Thus, Strong does not teach the SP required by sequences (2) and (3) recited in amended claim 1.

With regard to sequence (1) recited in claim 1, Strong does not teach an HLA-E chimeric molecule with a sequence (a) replacing all of the $\alpha 2$ domain of an HLA-E molecule with all of an $\alpha 2$ domain of an HLA-G1 molecule or (b) replacing a part of the $\alpha 2$ domain of the HLA-E molecule including serine 147 with a corresponding part of the $\alpha 2$ domain of the HLA-G1 molecule including cysteine 147, as in amended claim 1. Strong merely teaches HLA-E molecules with arginine 107 of the $\alpha 2$ domain replaced with glycine (position 107 of the amino acid sequence of HLA-G is held by glycine).

Applicants respectfully request that the rejection of claim 1 under § 102(b) be withdrawn.

Claim 1 stands rejected under 35 U.S.C. § 102(a) as being anticipated by Matsunami et al., "Modulation of the ALPHA 1 and 2 Domain Sequence of the HLA-E Gene Up-Regulates Its Expression and Function," Transplantation, Vol. 78, No. 2, page 157, Abstract O401, July 24, 2004 (hereinafter the "Matsunami Abstract"). Applicants respectfully traverse this rejection.

The Office Action indicated that the Matsunami Abstract is considered prior art, because three of the abstract's co-authors (T. Kusama, T. Kubo and R. Shirakura) are not named as inventors in the present application and a certified English translation of JP 2003-374944 (to which the present application claims priority) has not been submitted.

Kusama, Kubo and Shirakura merely acted under the direction and supervision of the inventors (*e.g.*, technicians following the instructions of those conceiving of the invention) in carrying out the work described in the Matsunami Abstract. Applicants are herewith filing a Declaration by Kasuyoshi Matsunami affirming this along with a certified English translation of JP 2003-374944 in order to obviate this rejection.

Alternatively, the Matsunami Abstract does not disclose the signal peptide having SEQ ID NO:21 recited in amended claim 1, sequences (2) and (3). The Matsunami Abstract also does

not teach sequence (1) of claim 1 to an HLA-E chimeric molecule (a) replacing all of the $\alpha 2$ domain of an HLA-E molecule with all of an $\alpha 2$ domain of an HLA-G1 molecule without an HLA-G1 leader sequence carrying the phenylalanine to valine mutation at position 10 or (b) replacing a part of the $\alpha 2$ domain of the HLA-E molecule including serine 147 with a corresponding part of the $\alpha 2$ domain of the HLA-G1 molecule including cysteine 147 without an HLA-G1 leader sequence carrying the phenylalanine to valine mutation at position 10. Thus, the teachings of the Matsunami Abstract are distinguished over amended claim 1.

Applicants respectfully request that the rejection of claim 1 under § 102(a) be withdrawn.

CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Stephanie A. Wardwell, PhD, Registration No. 48,025, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: March 29, 2011

Respectfully submitted,

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Attachments: Declaration of Kasuyoshi Matsunami
Certified English translation of priority document JP 2003-374944